

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY



(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 05 DEC 2005

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|--|---|---|
| Applicant's or agent's file reference<br>15655PCT00  | <b>FOR FURTHER ACTION</b> See Form PCT/PEA416   |   |
| International application No.<br>PCT/DK2004/000728   | International filing date ( <i>day/month/year</i> )<br>21.10.2004   | Priority date ( <i>day/month/year</i> )<br>24.10.2003 |
| International Patent Classification (IPC) or national classification and IPC<br>B29C65/00, A61F5/448   |   |   |
| Applicant<br>COLOSPLAST A/S ET AL.   |   |   |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 9 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> <i>sent to the applicant and to the International Bureau</i> a total of 5 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> <i>(sent to the International Bureau only)</i> a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> |   |   |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>  |   |   |
| Date of submission of the demand<br><br>04.07.2005   | Date of completion of this report<br><br>06.12.2005   |   |
| Name and mailing address of the International preliminary examining authority:<br><br> European Patent Office - P.B. 5818 Patentlaan 2<br>NL-2280 HV Rijswijk - Pays Bas<br>Tel. +31 70 340 - 2040 Tx: 31 651 epo nl<br>Fax: +31 70 340 - 3016  | Authorized Officer<br><br>Germano, A<br><br>Telephone No. +31 70 340-4202  |   |

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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

|      |  |
|------|--|
| 2-10 | as originally filed                              |
| 1    | received on 04.07.2005 with letter of 29.06.2005 |

**Claims, Numbers**

|      |  |
|------|--|
| 1-14 | received on 04.07.2005 with letter of 29.06.2005 |
|------|--|

**Drawings, Sheets**

|         |                     |
|---------|---------------------|
| 1/3-3/3 | as originally filed |
|---------|---------------------|

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. IV Lack of unity of invention**

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1. ☐ In response to the invitation to restrict or pay additional fees, the applicant has:
- ☐ restricted the claims.
  - ☐ paid additional fees.
  - ☐ paid additional fees under protest.
  - ☐ neither restricted nor paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
  - ☐ not complied with for the following reasons:
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
  - ☐ the parts relating to claims Nos. .

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

|                               |             |       |
|-------------------------------|-------------|-------|
| Novelty (N)                   | Yes: Claims | 1-11  |
|                               | No: Claims  | 12-14 |
| Inventive step (IS)           | Yes: Claims |       |
|                               | No: Claims  | 1-14  |
| Industrial applicability (IA) | Yes: Claims | 1-14  |
|                               | No: Claims  |       |

2. Citations and explanations (Rule 70.7):

**see separate sheet**

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

**see separate sheet**

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**Box No. VIII    Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item IV**

**Lack of unity of invention**

1. The application refers to five different inventions and therefore fails to meet the requirements of Rule 13.1 PCT.

The five different inventions referred to in the application are:

- a) a method for preparing a body side mounting wafer according to claims 1 to 6,
- b) a body side mounting wafer according to claims 7, 8 and 10,
- c) a body side mounting wafer according to claims 9 to 11,
- d) an apparatus for performing the method of claims 1 to 6, according to claims 12 and 13, and
- e) an apparatus for assembling the body side wafer of claims 7 to 13, according to claim 14.

- 1.1 According to Rule 13.1 PCT, an International Application may relate only to one invention, or to a group of inventions (generally defined in different independent claims) so linked as to form a single general inventive concept.

In the second case, the concept linking the inventions finds expression in the different independent claims according to the different inventions in terms of the same or corresponding technical special features, wherein the expression "technical special features" means the technical features which involve an inventive contribution over the prior art, see Rule 13.2 PCT.

- 1.2 In the present case the same or corresponding technical feature of independent claims 1, 7, 9, 12 and 14, namely the body side mounting wafer having first and second parts, the parts having first and second surfaces, attaching means, welds by electromagnetic radiation, fastening means, are all disclosed in the available prior art, see for example WO-A-02/00144 and US-A1-2003/093042.

The feature that "at least part of one zone being aligned with the attaching/fixing means of the first and second parts" is disclosed in WO-A-02/00144, see page 3,

lines 14-22 and fig. 5. Therefore the feature is per se not new and cannot involve an inventive contribution over the prior art. Moreover the feature is mentioned only in claim 1 and is conspicuously absent in claims 7, 12 and 14. Also the feature of claim 9 "the one....of the zones" is disclosed in at least said prior art and, moreover, does not appear to correspond to the feature of claim 1 cited above.

Therefore said common or corresponding technical features are not only not inventive, but even not new.

The remaining features of the claims are different and directed to the solution of different problems, and therefore are not "corresponding" features.

Therefore no inventive concept links the inventions according to the independent claims and the application does not meet the requirements of Rule 13.1 PCT.

- 1.3 However, in view of Rule 68.1, no extra fees are requested for extending the substantive examination to the groups of claims cited above.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

2. Document WO-A-02/00144 describes a method of preparing a body side mounting wafer which differs from the method described in claim 1 only in that said document does not clearly specify that first surface of the first part of the wafer is provided with one or more means adapted to be attached to or fixed to a body part of a person.
- 2.1 It has to be underlined that said WO-A-02/00144 discloses the feature that "at least part of one zone being aligned with the attaching/fixing means of the first and second parts", see point 1.2 above.
- 2.2 Claim 1 refers to a method of preparing a body side mounting wafer. The method does not comprise an ostomy bag and does not refer to the attachment of an ostomy

bag to the wafer as being part of the matter of the claim.

However, even if such attachment were introduced in the claim, it would not involve a difference over the prior art since it is disclosed in WO-A-02/00144, see fig. 5 and the relevant description.

Therefore the only feature of claim 1 which is not expressis verbis mentioned in said prior art is that one or more means adapted to be attached to or fixed to a body part of a person is provided on the first surface of the first part of the wafer.

In view of this difference the subject-matter of claim 1 is new and meets the requirements of Art. 33(2) PCT.

2.3 However, this feature is per se obvious and is described for the same purpose in the prior art, see for example US-A-2003093042. This document refers to an ostomy carrier device comprising a flexible adhesive base plate with an opening for securing the carrier device to a patient's skin around a stoma, as well as a circumferential mounting flange made of a flexible material and being adapted for removable and adhesive connection with a coupling element of an ostomy collecting bag, see paragraph 0001 and fig. 1. The means adapted to be attached to or fixed to a body part of a person is provided on a first surface of said flexible adhesive plate. In view of that the subject-matter of claim 1 does not involve an inventive step and does not meet the requirements of Art. 33(3) PCT.

2.4 The features of dependent claims 2 to 6 are described for the same purpose in the above mentioned WO-A-02/00144, Therefore claims 2 to 6 do not involve an inventive step and do not meet the requirements of Art. 33(3) PCT as well.

3. The same document WO-A-02/00144 describes a body side mounting wafer which differs from the wafer described in independent claim 7 only in that said document does not clearly specify that first surface of the first part of the wafer is "adapted to be attached to or fixed to a body part of a person".

In view of this difference (and insofar as this difference may be understood, see item VIII), the subject-matter of claim 7 is new and meets the requirements of Art. 33(2)

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- 3.1 However, this feature is per se obvious and is described for the same purpose in the prior art, see for example US-A-2003093042. In view of that the subject-matter of claim 7 does not involve an inventive step and does not meet the requirements of Art. 33(3) PCT.
- 2.2 The features of dependent claims 8, 10 and 11 are suggested for the same purpose in the above mentioned WO-A-02/00144, Therefore claims 8, 10 and 11 do not involve an inventive step and do not meet the requirements of Art. 33(3) PCT as well.
3. The same considerations apply for independent claim 9 and its dependent claims 10 and 11, which therefore do not meet the requirements of Art. 33(3) PCT.
4. The apparatus described in claims 12 to 14 is completely anticipated by the disclosure of said WO-A-02/00144. The particular use specified in the claims does not involve any technical difference vis à vis the apparatus described in the available prior art. These claims therefore do not meet the requirements of novelty of Art. 33(2) PCT.

**Re Item VII**

**Certain defects in the international application**

5. Contrary to the requirements of Rule 6.3(a)(I) and (ii), the independent claims are not shaped in the two part form.
6. In order to comply with the requirements of Rule 5.1(a)(ii) the description should have disclosed the invention as claimed.

**Re Item VIII**

**Certain observations on the international application**



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(SEPARATE SHEET)**

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7. The references in claims 1, 7, 9, 13 "adapted to (be attached or provide)" are not clear since they merely state the purpose of a feature without defining a choice among the several technical features which may be used for that purpose. In view of that these features cannot involve a difference against the prior art.

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## AN OSTOMY MOUNTING WAFER AND A METHOD OF PREPARING IT

The present invention relates to an ostomy wafer which is the part of an ostomy bag set mounted to the person and to which detachable ostomy bags may be mounted.

5 Normally, in order to obtain suitable flexibility, ostomy mounting wafers are prepared by fixing two parts to each other, where one part is adapted to be fixed to the person and the other part is adapted to form a landing zone for the ostomy bag. These parts are attached at the ostomy opening. However, this attachment must both be strong and sealed in order to prevent leaking. ATTACHMENTS OF THIS TYPE MAY BE SEEN IN WO 02/00144, US 2003/093042 AND EP 1108404.

10 Hitherto, this assembly/sealing has been performed by either using adhesives or heat welding.

Using adhesives provides a wider range of possibilities as to the actual shape of the attachment area and the thickness of the materials at the zones of attachment. However, for a number of reasons, the use of adhesives has been rejected as the proper way of attaching these parts. One such reason is the fact that the adhesive may present an environmental  
15 problem. Also, the use of adhesives adds a number of demands as to the adhesive and other materials useable. In addition, the long term stability of the adhesive connection is questionable.

Heat sealing/welding, on the other hand, avoids the use of adhesives but it results in the parts being deformed at the sealing due to the heat and pressure applied. In addition, the  
20 materials must fulfil certain requirements as to melting points and in particular the material thicknesses in the welding zone. Thus, both the dimensions required by the welding and the undesired dimension changes caused by the welding will provide weak zones and generally prevent the element from being useful for connection purposes in the area around the welding zone.

25 The present invention relates to a manner of attaching these parts in a manner where thicknesses may vary within much wider boundaries, where the outer surfaces at the attachment zones may be used for e.g. fastening the bag, and where a much wider selection of materials may be applied.

30 In a first aspect, the invention relates to a method of preparing a body side mounting wafer for attachment to a person and an ostomy bag, the method comprising:

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## CLAIMS

1. A method of preparing a body side mounting wafer for attachment to a person and an ostomy bag<sup>(12)</sup>, the method comprising:

- 5       -       providing a first part having a first surface having one or more means adapted to be attached to or fixed to a body part of the person<sup>(5)</sup>, and a second, opposite, surface, the first part having a first absorption coefficient at a predetermined wavelength of electromagnetic radiation,
- 10       -       providing a second part having a first surface having one or more means adapted to be attached to or fixed to the ostomy bag and a second, opposite, surface, the second part having a second absorption coefficient at the predetermined wavelength of electromagnetic radiation, the first and second absorption coefficients being different,
- 15       -       positioning the first and second parts so as to abut at one or more zones of the second surface of the second part and of the first part, at least part of one zone being aligned with the attaching/fixing means of the first and second parts, and
- 20       -       providing electromagnetic radiation, comprising radiation having the predetermined wavelength, through that of the first and second parts having the lowest absorption coefficient to the one or more zones so as to heat the other of the first and second parts at the one or more zones in order to, upon cooling, fix the first and second parts to each other.

2. A method according to claim 1, wherein the first part has a first opening, the second part has a second opening, and wherein the positioning step comprises positioning the first and second parts so that the first and second openings coextend.

25   3. A method according to claim 2, wherein the step of providing the second part comprises providing a second part where the attaching/fixing means comprise a surface adapted to engage an adhesive part of the ostomy bag, the surface extending to an edge of the second opening and wherein at least one of the one or more zones is positioned in a vicinity of the edge of the second opening.

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4. A method according to any of the preceding claims, wherein the step of providing that of the first and second parts having the highest absorption coefficient comprises providing the respective part with:

- a material having the first or second absorption coefficient at least at the one or more zones, and,
- at other parts of the respective part, another material having a third absorption coefficient at the predetermined wavelength.

5. A method according to any of the preceding claims, wherein the predetermined wavelength is determined within the interval of 0.7-6 $\mu$ m.

10 6. A method according to any of the preceding claims, further comprising, during the step of providing the radiation, maintaining, using a fastening means, the first and second parts in the abutting position, the step of providing the radiation comprising providing the radiation through the fastening means.

15 7. A body side mounting wafer for attachment to a person and an ostomy bag, the wafer comprising:

- a first part having a first surface adapted to be attached to or fixed to a body part of the person and a second, opposite surface,

- a second part having a first surface adapted to be attached to the ostomy bag and a second, opposite surface,

20 - one or more welds formed at one or more welding zones between the second surfaces of the first part and the second part, at least one weld zone extending over a first distance in a radial direction,

wherein the first surface of the second part is at least substantially smooth at the at least one weld zone and over a second distance extending over the at least one weld zone, the second distance extending in the radial direction and being at least 1.5 times the first distance.

8. A body side mounting wafer according to claim 7, wherein no 2 mm part of the first surface of the second part, in a cross section along the radial direction and over the second distance, has any part deviating more than 0.2 mm from a flat shape fitted to the 2 mm part.

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9. A body side mounting wafer for attachment to a person and an ostomy bag, the wafer comprising:

- a first part having a first surface having one or more surfaces or elements adapted to be attached to or fixed to a body part of the person and a second, opposite surface,
- a second part having a first surface having one or more surfaces or elements adapted to be attached to the ostomy bag and a second, opposite surface,
- one or more welds formed at one or more welding zones between the second surfaces of the first part and the second part,

wherein the one or more surfaces or elements of the first surface of the second part is aligned with at least part of the zones.

10. A body side mounting wafer according to any of claims 7-9, wherein:

- the first part has a first opening,
- the second part has a second opening,
- the zones being positioned in a vicinity of the edge of the second opening.

11. A body side mounting wafer according to claim 9, wherein the attaching/fixing means of the second part are adapted to snap-fit to corresponding means on the ostomy bag.

12. An apparatus for performing the method of any of claims 1-6, the apparatus comprising:

- fastening means for receiving and holding the first and second parts in the abutting relationship and
- means for providing the radiation to the one or more zones.

13. An apparatus according to claim 12, wherein the radiation providing means are adapted to provide the radiation through the fastening means.

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14. An apparatus for assembling a body side wafer according to any of claims 7-13, the apparatus comprising:

- <sup>(22)</sup> fastening means for maintaining the first and second parts in a <sup>(14)</sup> <sup>(16)</sup> predetermined, abutting relationship and
- 5 - <sup>(18)</sup> means for providing electromagnetic radiation to the zone(s) to form the weld(s).  
<sup>(16)</sup>